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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,864	03/13/2002	John M. Barker	P02467US1	4471
65008	7590	05/02/2007		
MDC INVESTMENT HOLDINGS, INC. c/o INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT	PAPER NUMBER
			3763	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No. 10/099,864	Applicant(s) BARKER ET AL.	
	Examiner Christopher D. Koharski	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-8,10-19,22-32,54-84 and 86-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-8,10-19,22-32,54-84 and 86-89 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 9/21/2006 in which claim 19 was amended. Currently claims 1,2,4,6-8,10-19, 22-32, 54-84 and 86-89 are pending for examination in this application.

Specification

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000))

Appropriate correction is required.

Claim Objections

Claim 32 is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function

language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

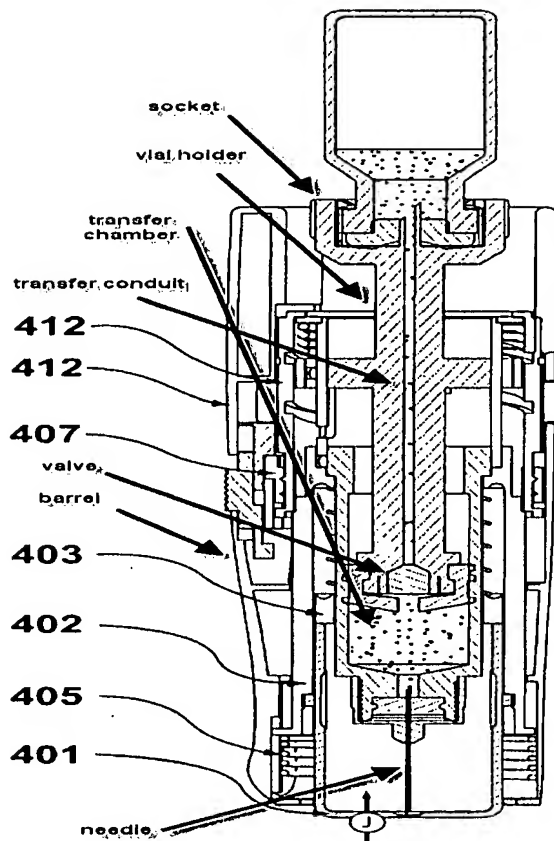
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 4, 6-8, 10, 11, 12-19, 22-32, 54-68, 61-71, 73-74, 76-84 and 87-89 are rejected under 35 U.S.C. 102(e) as being anticipated by Knauer (6,607,508). Knauer discloses a vial injector device.

Regarding claims 1-2, 4, 6-8, 10, 11, 12-19, 22-32, 54-68, 61-71, 73-74, 76-84 and 87-89, Knauer discloses a medical device (600) (Figure 1) for injecting medicinal fluid (col 3, ln 60-70) comprising a hollow barrel (400) (Figure 2), a vial holder (near 300) displaceable within the barrel (400) having a socket (near 101) configured to receive a vial (100) with a rearward fixed wall and a fixed pierceable wall (101-102), a pressuring element (near 303), a needle (201) having a sharpened tip operable between an exposed portion and a shielded position (Figures 7-8) with a biasing element to control the needle retraction (405) and the needle retainer (near 407, 412) with an activation surface (401), a transfer chamber (near 403) within the barrel for receiving the medicinal fluid from the vial, wherein the transfer chamber is adapted to be in fluid communication with the needle (201), a seal (305) operable to expel the medicinal fluid from the chamber through the needle, wherein after use the needle is disposed in the shielded position (col 3, ln 45-60) (Figures 1-11) (see marked up figure below).

Additionally, Knauer discloses a transfer conduit configured to extend between the vial to the transfer chamber (Figure 4) with the vial holder being partially disposed in the barrel (Figure 4), an air-pump chamber (near 303) comprising a piston capable of pumping air into the vial and capable of (303) expelling medicine out of the transfer chamber through the needle (201), several pierceable seals (102, 305) located through the fluid communication pathway to provided fluid tight seals, and several releasbly locking stop mechanisms that (near 302, 407, 409) that lock the vial holder to the barrel (Figures 1-11).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12, 59, 75 and 86 are rejected under 35 U.S.C 103(a) as being unpatentable over Knauer in view of Broden (4,972,843). Knauer meets the claim limitations as described above except for a sliding valve assembly for controlling flow through the system.

However, Broden teaches a sample taking system.

Regarding claims 12, 59, 75 and 86, Broden teaches a medical system comprising a vial (16), a barrel (18), a needle (2) and a slidable valve assembly (10) (Figure 1).

At the time of the invention, it would have been obvious to incorporate the slidable valve assembly of Broden to the system of Knauer to allow for a user defined flow control element. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Broden (see abstract).

Claim Rejections - 35 USC § 103

Claim 72 is rejected under 35 U.S.C 103(a) as being unpatentable over Knauer in view of Reynolds (4,861,335). Knauer meets the claim limitations as described above except for the socket and holder being displaceable relative to the piston.

However, Reynolds teaches a syringe cartridge injector.

Regarding claim 72, Reynolds teaches an injector with a barrel (4), a holder (9), a vial (10), a needle (1) wherein a plunger (5) and the holder are displaceable relative to

each other (see Figures 2-3) to allow for fluid communication between the vial and exit needle (Figures 1-9).

At the time of the invention, it would have been obvious to add the movable piston element of Reynolds to the system of Knauer in order to allow for multiple stage activation and sealing between the plunger and holder. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Reynolds.

Response to Arguments

Applicant's arguments, see remarks, filed 9/21/2006, with respect to the rejection(s) of claim(s) 1,2,4,6-8,10-19, 22-32, 54-84 and 86-89 under Boitch et al. (PGPUB 2004/0111063) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Knauer (6,607,508).

Suggested Allowable Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests the addition of/ further defining the different piston type elements and the different chambers created (48, 50, 65, 60) (see Applicant's Figure 1) to the independent claims of Applicant's current application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

4/29/07



Christopher D. Koharski
AU 3763